To: Minister Hunt
Subject: Cardiac Devices Registry
Critical date: 7 December 2017.

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Recommendation/s:	
1. Note	**1. Noted**
2. Agree to progress option 1	**2. Agreed/Not agreed/Please discuss**
3. Note	**3. Noted**
Signature …..……	**Date:** / /
Comments:	

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Issues:

1. An independent review of the Cardiac Device Registry (CDR) (**Attachment A**) has identified that ACOR has not met its contractual requirement to establish a clinical quality registry (CQR)[1] for cardiac devices.

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[1] CQRs are organisations that systematically monitor the quality (appropriateness and effectiveness) of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information. The information is used to identify benchmarks, significant outcome variance, and inform improvements in healthcare quality.

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Independent Review

In accordance with the CDR Contract for Services, an independent review of the CDR was undertaken to assess the effectiveness of the current arrangements, identify options to improve or modify the arrangements, and provide advice on strengthening future performance. The Department contracted HealthConsult Pty Ltd to undertake the review in June 2017 and the final report was provided on 26 October 2017.

HealthConsult also reviewed the arrangements for the ABDR, however no significant issues were identified.

HealthConsult identified that the strengths of the CDR are:

- Ability to link with other registries: it has been designed with the ability and functionality to link with existing registries including with other existing cardiac databases such as state based registries; and
- Stringent security protocols: all patient identified data is submitted through the Secure Report Depot, which is in line with best practices as per the CQR operating principles.
- Quality infrastructure for data provision: The CDR has a governance structure in place, accessible data collection forms, a documented minimum data set with documented data definitions, a detailed user manual and a number of Policies and Standard Operating Procedures.

The key issues identified in the review by HealthConsult are:

- Key data limitations: The CDR does not meet the requirements of the Commission's national *Operating Principles for Clinical Quality Registries*, as specified in the Contract for Services. It is therefore unable to analyse the device data in a way that is relevant for stakeholders, including clinicians and patients.
    - ACOR has proposed that the CDR could merge with an ACOR-owned cardiac procedure registry to become a CQR. The Department has previously explored this option and determined that the cardiac procedure registry is not fit for purpose, costly and has problematic intellectual property issues.
- Very low uptake of participating sites: There are 1194 patient records in the CDR provided by 43 clinicians across six sites. This represents less than five percent of eligible sites contributing data. Only 4 states are represented: NSW, QLD, SA and the ACT.
    - The target specified in the Contract for Services is for 100% participation of all facilities/clinicians performing cardiac implantation procedures across all jurisdictions in Australia.

These findings are the result of:

- Poor engagement with key stakeholders: ACOR has not engaged effectively with clinicians, the Australian and New Zealand Society of Cardio Thoracic Surgeons Australian and New Zealand (ANZSCTS)[3] or their State and Territory counterparts (including Victorian Cardiac Outcomes Registry, the Coronary Angiogram Database of South Australia), to promote greater participation in the CDR and leverage the success of State and Territory based registries.
    - State-based cardiac outcomes registries currently capture data from 41 sites (or 32% of total eligible sites).
- Role confusion: The majority of stakeholders are not sure if the CDR is a device register or a CQR. ACOR is also not clear about its role despite it being clear in the Contract for Services that the CDR should be a CQR.

A list of all the key findings from the independent review is at **Attachment C**.

The review provides options to address the identified problems. These include:

- ACOR to collect additional information in the CDR to comply with the Commission's CQR principles.
- Discontinue the CDR and start a new registry.
- Merge the CDR with ACOR's cardiac procedures registry.

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Attachment C

List of Findings

Below are the findings that have resulted from this Review.

Aims and objectives of the CDR

F1 The aims and objectives of the CDR are well documented and align with the relevant Operating Principles within the ACSQHC Framework for Australian Clinical Quality Registries, reflecting best practice.

F2 There is strong support across all stakeholder groups involved in the implantation of cardiac devices for the documented aims and objectives of the CDR.

F3 There are mixed and conflicting views amongst stakeholders on the purpose of the CDR. One view (majority of stakeholders) is that the CDR has been set up as a recall registry and the other view is that the CDR should be a fully functioning CQR. The latter view is clearly reflected in the Contract for Services and the associated CDR documentation.

F4 The CDR is not a CQR, as it does not include the required outcomes and procedure data. The addition of procedures and outcomes data would result in a more comprehensive dataset that is consistent with a fully functioning CQR, and would provide greater ability to analyse cardiac device data in a way that is more relevant to stakeholders.

Effectiveness of the design, development, implementation and operation of the CDR

F5 The data collection approach implemented at each of the contributing sites is different. This practice does not adhere to the relevant Operating Principles for CQR development. Adopting a more consistent approach would assist the collection of high quality and complete datasets.

F6 The CDR is operated in parallel with the CPR to minimise workload at sites. The information in the two Registries is manually transferred and can be manually linked. The process is not efficient. It is time consuming for Registry staff and has also resulted in issues around poor data quality.

F7 The process for contributing data to the CDR creates a high resource burden at participating sites of up to 10 minutes per procedure. Current efforts to make the data collection process more efficient should be pursued.

F8 The CDR meets the data security requirements as specified in the relevant Operating Principles for CQR development. Access to the Registry information is restricted through the Secure Report Depot, and data access and reporting requires Steering Committee endorsement.

F9 The CDR data quality assurance activity is in its infancy and is further evolving with the development of the Registry. There is evidence that the processes for monitoring the accuracy and completeness of data are in place, and it is expected that they will be implemented and further refined as the dataset grows.

F10 The CDR reporting processes are still in the development phase, due to the infancy of the Registry. There is evidence of a structured process, which is likely to produce the information required. There is also evidence that Registry has consulted with contributing sites to understand their needs for performance monitoring reports.

Registry support and infrastructure

F11 The CDR provides adequate support to participating sites when required and for the most part, the supporting documentation for the CDR serves its purpose.

F12 The layout of the paper based data collection forms can be improved without compromising the data collected. This opportunity is evidenced by one of the contributing sites, which has developed a two page form that collects all data elements required (although it also covers the CPR).

Data Collected

F13 The CDR has a well-developed minimum dataset with associated data definitions to support the provision and interpretation of the required data. However, these documents are currently only available through the Secure Report Depot, and are not available to the general public.

F14 Input into the development of the minimum dataset was limited to a select number of clinicians and stakeholders. Not all of the relevant stakeholders were consulted, and in some instance, it appears that advice provided was not addressed by the Registry.

F15 The lack of a shared understanding around the aim and objectives of the CDR is reflected in the conflicting views on whether the data elements collected meet the aims and objectives of the CDR.

F16 The CDR does not meet the relevant Operating Principles of a CQR or the requirements of the Contract for Services in respect of the adequacy of the data collected. Currently, sufficient data for risk adjustment and outcomes reporting can only be obtained through the use of a secondary data source (i.e. existing procedures/outcomes registries).

Organisation and governance arrangements

F17 The CDR has a governance structure that is set up in line with the relevant CQR Operating Principles. Operationally, Registry staff have identified the opportunity to improve and optimise the output of the CDR Management Committee, and are in the process of implementing changes.

F18 The CDR Steering Committee should consider expanding its membership to include representatives from each of the State-based registries and Registry custodians (SAHMRI) to promote greater participation and provide immediate access to additional Registry development and operational expertise.

Level of registry skills and experience

F19 The CDR, particularly through the SAHMRI, has access to staff with the required level of Registry skills and expertise.

F20 The addition by the SAHMRI of Registry staff with the Joint Replacement Registry experience is a positive, and the learnings gained from establishing and running a highly successful registry will assist the SAHMRI in the development and delivery of the CDR.

Stakeholder engagement with the CDR

F21 The CDR has not met the participation targets as set in the Contract for Services. Less than five percent of eligible sites are currently contributing data, with representation from only NSW, QLD, SA and the ACT.

F22 The CDR has a low level of engagement from the ANZSCTS. Currently, there is no surgical valve data available in the CDR.

F23 The CDR has a low level of engagement from clinicians, particularly those contributing to State-based registries. Whilst there is evidence to suggest clinicians are willing to contribute to the CDR, this interest has not been reflected through site or clinician recruitment and participation.

Contract progress reporting requirements

F24 The CDR has met the progress reporting requirements required under the Contract for Services.